



Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-15-14AQA]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be

collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

The Enhanced STD Surveillance Network (eSSuN) - NEW - Division of STD Prevention (DSTDP), National Center for HIV/AIDS, Viral Hepatitis, STD, and TB prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Enhanced STD surveillance network Project is an active STD sentinel surveillance network comprised of 10 surveillance sites including Baltimore City Health Department, California Department of Public Health, Florida Department of Health, Massachusetts Department of Public Health, Minnesota Department of Health, Multnomah County Health Department, New York City Department of Health & Mental Hygiene, Philadelphia Department of Public Health, San Francisco Department of Public Health, and Washington State Department of Health.

The purpose of eSSuN is to be a robust platform for the identification of STD trends, monitor STD epidemiology and evaluate the effectiveness of public health interventions through active surveillance collection, reporting, analysis, visualization (e.g., mapping) and interpretation of disease information.

The objectives of the eSSuN project are (1) provide a dataset of supplemental information on gonorrhea case reports of STDs of interest; (2) provide geographic information on case reports of STDs of interest for investigating social determinants of STDs; (3) monitor screening coverage for chlamydial infection among young women in sentinel clinical settings; (4) monitor STD screening, incidence, prevalence,

epidemiologic and health care access trends in populations of interest such as men-who-have-sex-with men (MSM), young people and persons diagnosed with gonorrhea; (5) monitor STD treatment and prevention service practices; (6) monitor selected adverse health outcomes of STDs; (7) evaluate and enhance local and state STD surveillance capacity; (8) enhance local STD-specific health information technology and epidemiologic capacity, and, (9) establish a core of exemplary state, tribal, territorial, county and/or city health department STD surveillance approaches to STD surveillance.

This project will utilize two distinct surveillance strategies to collect information. The first strategy employs facility-based sentinel surveillance, which will abstract standardized data from existing electronic medical records for all patient visits to participating STD clinics and female patients aged 15-44 years of age visiting participating family planning/reproductive health clinics and other facilities (school-based clinics and federally qualified healthcare centers) during the project period. The second strategy is population-based STD surveillance among a random sample of reported gonorrhea cases. Sampled cases will be contacted for standardized interview and the sample fraction will be 250 completed enhanced investigations or up

to 2.5% of total morbidity if annual cases exceed 10,000 cases. Enhanced investigations will also include verification of treatment and an internal health department record review (performed on either all cases or on the sampled cases).

For the facility-based component of eSSuN, participating sites have developed common protocols stipulating data elements to be collected, including patient demographics, clinical, risk and sexual behaviors. The specified data elements are abstracted by clinic staff from existing electronic medical records for; (1) all patient visits to participating STD clinics, (2) female patients aged 15 - 24 at participating family planning/reproductive health clinics and, (3) visits of female patients aged 15-44 at school-based clinics and those attending federally qualified health centers (FQHCs) specifically for family planning services.

Some of the participating facilities are satellites clinics of large network providers where clinical data systems are centralized. Hence, there are a total of 22 unique clinic data managers that will be abstracting the facility data. Each of the 22 clinic data managers will spend 3 hours to extract and transmit data to local/state health departments. Individual patient records are de-identified (all patient-specific identifiers are removed) by clinic staff before being transmitted to health departments, who

recode the data into standardized formats before being transmitted to CDC through secure file transport mechanisms. Data transmission will occur on a monthly basis. Each eSSuN site will spend 16 hours to recode and transmit the data to CDC every month. At CDC, data will be aggregated across all participating sites in a common data structures and formatted for analysis.

For the population-based surveillance component, a random sample of individuals residing within participating jurisdictions and reported with gonorrhea will be interviewed using locally designed interview templates following standardized data protocols. Enhanced data collection includes detailed information on demographic characteristics, behavioral risk factors and clinical history of persons with gonorrhea. Each of the 10 sites will interview a minimum of 250 persons (or up to 2.5% of total morbidity if annual GC cases exceed 10,000 cases) and each interview is expected to take 10 minutes per person. Interview data for the population-based component will be collected through telephone administered or in-person interviews conducted by trained interviewers in the 10 eSSuN sites. These data will be directly entered into existing STD surveillance information systems at each health department. Data will be locally extracted, de-identified and recoded into

standardized formats prior to being transmitted to CDC through secure file transport mechanisms on a monthly basis.

Patient participation in the interview is voluntary and refusal to participate has no impact on other STD services the local health provides to persons diagnosed with gonorrhea. There is no cost to the respondents beyond their time and no compensation for participation.

Both components of eSSuN are designed to (1) integrate traditional surveillance methods with innovative data management technologies to produce high-quality, timely surveillance and epidemiologic data, (2) provide valuable information to direct public health STD prevention and control efforts, (3) enhance understanding of the community burden of disease, (4) identify syndemic patterns and population at greatest risk, and, (5) monitor long-term health consequences of STDs. The eSSuN surveillance platform allows CDC to establish and maintain common standards for data collection, transmission, and analysis, and to build and maintain STD surveillance expertise in 10 state or city health departments. Such common systems, established mechanisms of communication, and in-place expertise are all critical components for timely, flexible, and high quality surveillance.

The total estimated annual burden is 2,854 hours of effort.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (Hours)
Clinic Data manager at clinic	Data Manager electronic Transmission Record Abstraction (No Form)	22	6	3
Health Department Data Manager	Case Reports (No Form)	10	12	16
Gonorrhea Patients sampled and interviewed	Patient Interview	3,225	1	10/60

Leroy A. Richardson
Chief, Information Collection Review Office
Office of Scientific Integrity
Office of the Associate Director for Science
Office of the Director
Centers for Disease Control and Prevention

[FR Doc. 2014-29715 Filed 12/18/2014 at 8:45 am; Publication Date: 12/19/2014]